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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,315	11/20/2003	Francesco Serino	GLM-1042A	9755
27316	7590 08/28/2006		EXAMINER	
GREGORY L. MAYBACK, P.A. 5722 S. FLAMINGO ROAD #232			ADAMS, AMANDA S	
	ERDALE, FL 33330		ART UNIT PAPER NUMBE 3731	
			DATE MAILED: 08/28/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/718,315	SERINO ET AL.			
		Examiner	Art Unit			
		Amanda Adams	3731			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 10 Ju	<u>ıly 2006</u> .				
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Disposit	ion of Claims					
4)⊠	Claim(s) 1-42 is/are pending in the application.					
	4a) Of the above claim(s) 1-9 and 23-42 is/are withdrawn from consideration.					
5)⊠	Claim(s) 10-21 is/are allowed.					
6)⊠	Claim(s) <u>22</u> is/are rejected.					
	Claim(s) is/are objected to.					
8)	Claim(s) are subject to restriction and/or	r election requirement.				
Applicati	ion Papers					
9)□	The specification is objected to by the Examine	r.				
10)	The drawing(s) filed on is/are: a) acce	epted or b) objected to by the	Examiner.			
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
	Replacement drawing sheet(s) including the correct	ion is required if the drawing(s) is ob	jected to. See 37 CFR 1.121(d).			
11)	The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority (	under 35 U.S.C. § 119					
	Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  Certified copies of the priority documents  Certified copies of the priority documents  Copies of the certified copies of the priority	s have been received. s have been received in Applicati	on No			
	application from the International Bureau	•	ed III tilis National Stage			
* 5	See the attached detailed Office action for a list	· · · · · · · · · · · · · · · · · · ·	ed.			
Attachmen		_				
	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4) 🔲 Interview Summary Paper No(s)/Mail D				
3) Infor	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date		Patent Application (PTO-152)			

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#### **DETAILED ACTION**

## **Priority**

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### Election/Restrictions

- 2. Claims 1-9 and 23-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected restriction groups and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 14, 2005.
- 3. Applicant's election with traverse of Group II and Species B (Fig. 5) in the reply filed on December 14, 2005, is acknowledged. The traversal is on the ground(s) that the species are each applicable to more than one of the groups listed in the restriction requirement. This is not found persuasive because a species can be applicable to more than one group in a restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parodi (US 6,423,032) in view of Dehdashtian et al (US 6,143,014) and further in view of Marin et al (US 5,697,948).

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- 3. Parodi discloses the invention substantially as claimed including a releasing balloon catheter comprising a tube (fig. 3A [45]) with a balloon ([46]), and a guiding balloon catheter comprising a sheath (fig. 3A [41]), a balloon ([42]) and a second tube acting as a connection for an inflating syringe ([44]). Parodi fails to disclose a dilator and an introducer as a part of the guiding balloon catheter apparatus.
- 4. However, Dehdashtian et al teach a dilator (col. 7, line 41) and an introducer (col. 7, lines 28-31) as components of the guiding balloon catheter. A dilator and an introducer facilitate easier insertion of a graft delivery system, reducing the size of the percutaneous incision. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added a dilator and introducer as a way of inserting and guiding the balloon catheter.
- 5. Neither Parodi nor Dehdashtian teach a cup-shaped connection between the tube and balloon of the releasing balloon catheter and an inflating syringe. However, Marin et al teach a cup-shaped connection between the tube and the balloon of the releasing balloon catheter (Figure 1A), and an inflating syringe (col. 7, line 16). Having a cup-shaped connection between a catheter and a balloon allows a smoother transition between components, and a connection is necessary if the catheter is to be used to inflate the balloon. Also, an inflating syringe is a common method of inflating a balloon

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through a catheter, Therefore it would have been obvious to use a cup-shaped connector and to provide an inflation syringe.

## Allowable Subject Matter

- 1. Claims 10 21 are allowed.
- 2. Regarding claims 10 and 16, the following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a stent-graft delivery system comprising all of the limitations specifically wherein there is a dilator fitted with a hemostatic valve, an introducer fitted with a valve, or a second tube running eccentrically outside a guiding balloon catheter which has a portion for connection to an inflating syringe, as set forth by the applicant. Parodi in view of Dehdashtian et al and further in view of Marin et al disclose the invention substantially as claimed except that they fail to teach a delivery system where a dilator fitted with a hemostatic valve, an introducer fitted with a valve, or a second tube running eccentrically outside a guiding balloon catheter which has a portion for connection to an inflating syringe.
- 3. Claims 11-15 depend from claim 10 and are thus allowable. Claims 17-20 depend from claim 16 and are thus allowable.

### Response to Arguments

4. Applicant's arguments with respect to claim 22 have been considered but are most in view of the new ground(s) of rejection.

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#### Conclusion

- 5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
  - US 5,275,622
  - US 5,733,299.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON PRIMARY EXAMINER